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Lawrence A. Nielsen
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3030 Cornwallis Road
Research Triangle Park, NC 27709

RE: Patent Term Extension
Application for
U.S. Patent No. 4,312,860

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,312,860 issued January 26, 1982, which claims the human drug product Exosurf Neonatal is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 1,030 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of December 20, 1990. Under 35 USC § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase)} + \text{Approval Phase} \\ &= 1/2 (1,723) + 168 \\ &= 1,030 \text{ days}\end{aligned}$$

Since the regulatory review period began after the original patent issue date, the entire period has been considered. No determination of a lack of due diligence was made.

The limitations of 35 USC § 156(g)(6) and the 14 year exception of 35 USC § 156(c)(3) do not operate to further reduce the period determined above.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,312,860 a certificate of extension, under seal, for a period of 1,030 days.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

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|---------------------|--|
| U.S. Patent No.: | 4,312,860 |
| Granted: | January 26, 1982 |
| Applicant: | John A. Clements |
| Owner of Record: | The Regents of The University of California |
| Title: | Lung Surfactant Compositions |
| Classification: | 514/78 |
| Product Trade Name: | Exosurf Neonatal |
| Term Extended: | 1,030 days |

C. E. Van Horn

Charles E. Van Horn
Patent Policy and Programs Administrator
Office of the Assistant Commissioner for Patents

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

RE: Exosurf Neonatal
FDA Docket No. 90E-0343